UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P O Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,359	07/30/2001	D. Wade Walke	LEX-0208-USA	1068

24231 7590 11/04/2003

LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
THE WOODLANDS, TX 77381-1160

EXAMINER	
MURPHY, JOSEPH F	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Applicati n No.	Applicant(s)	
	09/918,359	WALKE ET AL.	
	Examin r	Art Unit	
	Joseph F Murphy	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *02 September 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT plac the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

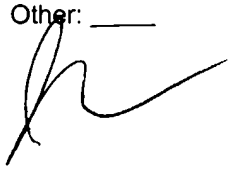
Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____



Continuation of 5. does NOT place the application in condition for allowance because: Applicant's arguments have been fully considered but they are not persuasive. The rejection of record set forth that the nucleic acid encoding the NHP polynucleotide has been isolated because of its similarity to known proteins and given the unpredictability of protein function from structural information.
Applicant argues that the nucleic acid of the instant claims can be used in diagnostic assays for polymorphisms, and that this is a real world utility. This asserted utility is credible but not specific or substantial. The specification discloses a number of polymorphisms present in the NHP gene. However, the specification does not disclose the nexus between any of these polymorphisms and any function of the expressed polypeptide. Applicant further argues that the asserted utility is specific because it cannot be applied to any polynucleotide other than the one claimed and that the rejection has confused the requirement for a specific utility with an alleged requirement for a unique utility. Applicant cites Carl Zeiss Stiftung v. Renishaw PLC, 945 F.2d 1173, 20 USPQ2d 1094 (Fed. Cir. 1991) which sets forth that "an invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications". However, Carl Zeiss is inapposite to the facts of the instant case. In Carl Zeiss, the district court had found that a claim to a probe containing a stylus which is mounted to a movable arm above a table which supports an object to be measured lacked utility because "the arbitrary presentation of part of an invention does not constitute a claim of a valid invention" and tha the claimed device could no function as a probe. See Carl Zeiss at 1180. In the instant case, however, the claims lack utility not because they are incomplete, and not because they do not set forth the best or only way to accomplish a result, and not because that are not unique, but because they do not have either a well-established utility or a specific and substantial asserted utility. Applicant asserts that the encoded protein is almost 100% identical to one that is annotated in GenBank as a calcium channel (AY029200). However, the annotated protein has not been shown to function as a calcium channel, and the art cited above teaches the assignment of function base on homology is inherently difficult, as evidenced by the references of Doerks, Brenner and Bork. Additionally, even if the AY029200 polynucleotide is found to function as a Calcium channel, the date of publication of the sequence is May, 1 2002, which is after the filing date of the instant application. In order for an asserted utility to be well-established, it must be well-established at the time of filing. Since the AY029200 polynucleotide is a post-filing reference, the asserted utility was not well-established at the time of filing.

The claims also do not have a specific and substantial utility because the specification does not disclose the nexus between any of the polymorphisms and any function of the expressed polypeptide. The alleged ability of the polymorphism to distinguish 50% of the human population in a forensic analysis is not a specific and substantial utility. There is no correlation disclosed between the presence o any of these polymorphisms and the effect of the presence of any of these polymorphisms on the risk of any disease or disorder, therefor this asserted utility is not specific. Significant further experimentation would be required of the skilled artisan to identify individuals with a disease or disorder or condition which correlates to the presence of one of the enumerated polymorphisms, therefore, since this asserted utility is not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial. Applicant cites In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) and argues that, as in Brana, the Examiner has confused "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption". Brana at 1442. However, Brana is inapposite to the facts of the instant case. Here, the claims lack utility not because they are not ready for use as a drug, but because they do not have either a well-established utility or a specific and substantial asserted utility. In this case all nucleic acids and genes are in some combination useful in polynucleotide arrays. Therefore, this is a utilit which would apply to virtually every member of a general class of materials, such as any collection of nucleic acids, but is only potential with respect to SEQ ID NO: 6. Because of this, such a utility is not a specific utility. The use of the claimed nucleic acid in structural analysis of the genome is not particular to the sequence being claimed because it would be applicable to the general class of cDNA's. Any partial nucleic acid prepared from any cDNA may be used for structural analysis of the genome. .

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600